OCT - 8 2003

510(k) Summary

K032437

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett
Date Prepared: August 4, 2003

2) Device name

Proprietary name: Chemstrip® 5 OB, Chemstrip® 7 and Chemstrip® 10 MD test strips
Common and Classification name: Urinary test system

3) Predicate device

The Chemstrip 5 OB, 7 and 10 MD test strips are equivalent to other urinalysis strips such as Bayer Multistix® 10 SG for use on the Clinitek 50 Urine Analyzer (K960546).

4) Device Description

The Chemstrip 5 OB test strip is a multi-parameter urinalysis test strip, which measures leukocytes, blood/hemoglobin, nitrite, protein and glucose in the urine.

The Chemstrip 7 test strip is a multi-parameter urinalysis test strip, which measures pH, ketone, leukocytes, blood/hemoglobin, nitrite, protein and glucose in the urine.

The Chemstrip 10 MD test strip is a multi-parameter urinalysis test strip which measures specific gravity, pH, ketones, leukocytes, blood/hemoglobin, nitrite, protein, urobilinogen, bilirubin and glucose in the urine.

5) Intended use

Multi-parameter test strips to measure certain constituents in the urine either visually or by using the Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip® 5 OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication of leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood and hemoglobin in urine.

6) Substantial equivalence – Similarities and Differences

The table shown below describes the similarities and differences between the Chemstrip 10 MD Urine Test Strip and the Chemstrip 5 OB and Chemstrip 7 urine test strips.

Feature	Chemstrip 10 MD Test Strips for use on the Chemstrip 101 Urine Analyzer (K983510)	Chemstrip 5 OB & 7 Test Strips for use on the Chemstrip 101 Urine Analyzer
Intended Use	The Chemstrip 10 MD urine test strip is a multi-parameter test strip used to measure certain constituents in the urine either visually or on the Roche Diagnostics Chemstrip 101 Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	**Same**
Constituents Detected	Specific Gravity, Leukocytes, Nitrite, pH, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Blood	**Reduced number of parameters**

Device Similarities and Differences

-Continued-

Feature	Chemstrip® 10 MD Test Strips for use on the Chemstrip 101 Urine Analyzer (K983510)	Chemstrip® 5 OB & 7 Test Strips for use on the Chemstrip 101 Urine Analyzer
Test Principle	Specific Gravity: In the presence of cations, protons are released by a complexing agent and produce a color change of the bromthymol blue indicator.	**Not offered on the 5 or 7**
	Leukocytes: Leukocytes in urine are detected by the action of esterase, present in granulocytic leukocytes, which catalyzes the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a color change.	**Same**
	Nitrite: Nitrite reacts with an aromatic amine to give a diazonium salt, which by coupling with a further compound, yields a red-violet azo dye.	**Same**
	pH: The test strip contains the indicators methyl red and bromthymol blue. These give clearly distinguishable colors over the pH range of 5-9.	**Same as the 7, but not offered on the 5**
	Protein: The detection of protein is based on the "protein error of pH indicators". The indicator 3',3",5',5"-tetrachlorophenol-3,4,5,6-tetrabromosulfophthalein yields a color change in a positive reaction.	**Same**
	Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method.	**Same**
	Ketones: Sodium nitroprusside and glycine react with acetoacetate and acetone in an alkaline medium to form a violet dye complex.	**Same as the 7, but not offered on the 5**

Device Similarities and Differences

-Continued-

Feature	Chemstrip® 10 MD Test Strips for use on the Chemstrip 101 Urine Analyzer (K983510)	Chemstrip® 5 OB & 7 Test Strips for use on the Chemstrip 101 Urine Analyzer
Test Principle	Urobilinogen: Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a red azo dye.	**Not offered on the 5 or 7**
	Bilirubin: Bilirubin detection is based on the coupling reaction of a diazonium salt (2,6-dichlorobenzene-diazonium-tetrafluoroborate) with bilirubin in an acid medium which yields a color change.	**Not offered on the 5 or 7**
	Blood: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide contained in the test paper. Intact erythrocytes hemolyze on the test paper and the liberated hemoglobin produces a green dot.	**Same**
Test Pad	The test papers are attached to the strip with a nylon mesh and certain test papers have an inert absorbent paper located between the test area and the strip.	**Same**

Device Similarities and Differences

The table shown below describes the similarities and differences between the Chemstrip 5 OB, Chemstrip 7 and Chemstrip 10 MD urine test strips and the Bayer Multistix® 10 SG for use on the Clinitek 50 Urine Analyzer (K960546).

Feature	Chemstrip® 5 OB, Chemstrip® 7 and Chemstrip® 10 MD Test Strips for use on the Chemstrip 101 Urine Analyzer	Bayer Multistix® 10 SG for use on the Clinitek 50 Urine Analyzer K960546
Intended Use	The Chemstrip 5OB, 7 and 10 MD urine test strip are multi-parameter test strips used to measure certain constituents in the urine either visually or on the Roche Diagnostics Chemstrip 101 Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	The Bayer Diagnostics Reagent Strips for Urinalysis are multi-parameter strips used to measure certain constituents in urine either visually or using the Clinitek family of Urine Chemistry Analyzers.
Constituents detected	Combinations of Specific Gravity, Leukocytes, Nitrite, pH, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Blood	Same
Sensitivity Claims	The following table summarizes the sensitivity data obtained with the Chemstrip Criterion II Urine Analyzer and the Chemstrip 101 Urine Analyzer. This table lists the level of analyte that is generally detectable as positive when tested with a contrived urine pool. Because of inherent variability in clinical urines, lower levels may be detected under certain conditions. (Note: Criterion II information remains the same as previously indicated in the Chemstrip 10 MD insert) **Reagent** / **Criterion II** / **Chemstrip 101** Bilirubin 1.0 mg/dL 0.8 - 1.5 mg/dL Blood 5 Ery/uL 5 - 20 Ery/uL Glucose 40 mg/dL 30 - 40 mg/dL Ketone 5 mg/dL 5 - 15 mg/dL Leukocytes 25 Leu/uL 30 - 35 Leu/uL Nitrite 0.05 mg/dL 0.06 - 0.10 mg/dL Protein 18 mg/dL 25 - 32 mg/dL Urobilinogen 0.4 mg/dL 1 - 2 mg/dL	The following table lists the generally detectable levels of analytes in contrived urine; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions. **Reagent** / **Sensitivity** Glucose 75-125 mg/dL glucose Bilirubin 0.4-0.8 mg/dL bilirubin Ketone 5-10 mg/dL acetoacetic acid Blood 0.015-0.062 mg/dL hemoglobin Protein 15-30 mg/dL albumin Nitrite 0.06-0.1 mg/dL nitrite ion Leukocytes 5-15 cells/hpf in clinical urine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 8 2003

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k032437
Trade/Device Name: Chemstrip® 5 OB, 7 and 10 MD Urine Test Strips
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: JIL; JRE; CEN; LJX; JIO: JMT; JIN; JJB; CDM; JIR
Dated: August 4, 2003
Received: August 7, 2003

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Chemstrip® 5 OB, 7 and 10 MD Urine Test Strips

Indications for Use:

Multi-parameter test strips to measure certain constituents in the urine either visually or by using the Roche Diagnostics Chemstrip 101 Urine Analyzer or Criterion II Urine Analyzer. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip® 5 OB, 7 and 10 MD urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication of leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood and hemoglobin in urine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032437

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)